

Applicants thus submit that the formal requirements of 37 C.F.R. § 1.67(a) have been met, and the objection may be withdrawn.

Rejections under 35 U.S.C. § 102

Claims 1-5, 9-11, 14-15, and 21 stand rejected for anticipation by Becerra. In the Office's view, paragraphs 0179, 0358, 0458, and 0462-0464 teach the limitations of independent claims 1 and 14. For a reference to be anticipatory, it must teach every limitation of a claim. Here, Becerra fails to teach step (a) of either claim 1 or claim 14, and Applicants therefore traverse the rejection.

Claims 1 and 14 are directed to methods for identifying a target for analgesic therapy. Both methods require analysis of first and second non-human subjects that have a *genetic-based difference in nociception*, as recited in steps (a). Becerra does not teach this step.

In support of the rejection, the Office has pointed to paragraph 0179 as teaching step (a). This paragraph recites:

In step 512, subjects are selected and screened for study. The subjects may be human, or animal, depending on the experimental question behind the experiments developed in step 510.

While this paragraph does disclose the use of non-human animals in studies, there is absolutely no teaching of the use of two non-human subjects that have a *genetic-based difference in nociception*, as required in step (a). Accordingly, Becerra is not anticipatory, and the rejection may be withdrawn.

As Becerra does not teach the limitations of step (a) of either independent claim rejected, it is not necessary to address the remaining arguments raised by the Office. Applicants reserve the right to address these arguments in the future, if necessary.

### Rejections under 35 U.S.C. § 103

Claims 6-8 12-13, 16-20 and 22-54 stand rejected for obviousness over Becerra, alone or in combination with Mogil. As stated in the M.P.E.P., the Office is required to provide factual findings and rationales to support an obviousness rejection. Applicants submit that the factual findings of record do not support a finding of obviousness.

The present independent claims are drafted in pairs in terms of the subjects involved, and Applicants traverse the rejection as it applies to each pair of claims as follows. As above, Applicants have presented arguments rebutting the rejection with respect to the independent claims, and it is therefore not necessary to address the remaining arguments raised by the Office. Applicants reserve the right to address these arguments in the future, if necessary.

#### *Claims 1 and 14*

The rejection of claims 6-8, 12-13, and 16-20 for obviousness relies on the assertion by the Office that Becerra teaches methods for identifying a target for analgesic therapy using two, non-human subjects that have a genetic-based difference in nociception, as recited in claims 1 and 14. As discussed above, while Becerra does teach the use of non-human animals in certain methods, it does not teach or suggest the use of two subjects that have a genetic-based difference in nociception, an element central to the claimed invention. Moreover, there is no reason to try the mice of Mogil in the experiments of Becerra, as Becerra does not teach the use of two, genetically distinct non-human subjects. This basis of the rejection may be withdrawn.

#### *Claims 22 and 42*

These independent claims require two non-human subjects, wherein one of the subjects expresses a transgene of interest. In rejecting these claims, the Office acknowledges that transgene expression in non-human subjects is not taught by Becerra. Rather, the Office relies on Mogil to supply the missing information, stating that the reference “teaches providing a first and a second non-human subject, said non-human

subject differing from said first non-human subject in its expression of a transgene of interest (Figure 1).” Applicants have reviewed Figure 1 of Mogil but find no reference to expression of a transgene by any of the strains depicted in that figure. According to Mogil, the strains studied were *inbred* mouse strains obtained from The Jackson Laboratory (see Abstract and Materials and Methods). Applicants have attached the explanation of the production of inbred mice strains from The Jackson Laboratory website. There is no indication in this information that any of the inbred strains studied in Mogil expresses a transgene. Accordingly, even if there is a basis for combining Becerra with Mogil, that combination would not lead one skilled in the art to the invention of claims 22 and 42. This basis of the rejection should be withdrawn.

#### *Claims 32 and 48*

These independent claims require two non-human subjects, where one of the subjects has at least one endogenous allele that is functionally disrupted or deleted. To support the rejection of these claims, the Office states that Mogil “teaches providing a first and a second non-human subject, said non-human subject differing from said first non-human subject in its expression of a transgene of interest (Figure 1).” Neither claim 32 nor claim 48, however, recites “expression of a transgene.” Accordingly, any teachings of Mogil on this point (of which Applicants found none) are irrelevant to the patentability of these claims. This final basis of the rejection should also be withdrawn.

Conclusion

Applicants submit that the claims are in condition for allowance, and such action is respectfully requested. Enclosed is a petition to extend the period for reply for three months, to and including February 22, 2008. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

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Respectfully submitted,

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